

(PCT Article 36 and Rule 70)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2005/001840

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-29 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 6-18 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1, 3, 5, 19-20 _____ received by this Authority on 09.12.2005
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets Fig. 1-4 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☒ the claims, nos. 2, 4 _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims <u>1, 3, 5-20</u>	YES
		Claims _____	NO
	Inventive step (IS)	Claims _____	YES
		Claims <u>1, 3, 5-20</u>	NO
	Industrial applicability (IA)	Claims <u>1, 3, 5-20</u>	YES
		Claims _____	NO
2.	Citations and explanations (Rule 70.7)		
	<p>Document 1: JP 8-173192 A (Hamamatsu Photonics K.K.), 9 July 1996</p> <p>Document 2: JP 2000-504213 A (Flinders Technologies Pty Ltd.), 11 April 2000</p> <p>Document 3: WO 01/081541 A2 (Research Development Foundation), 1 November 2001</p> <p>The inventions set forth in claims 1, 3 and 5 to 18 do not involve an inventive step in the light of documents 1 to 3 cited in the international search report.</p> <p>Documents 1 to 3 set forth in situ PCR wherein a sample containing cells is immobilized on a support, the nucleic acid contained in said sample is exposed by treatment which uses a surfactant and/or enzymes, the nucleic acid in said sample on said support is amplified, and a judgment is made as to whether the amplified nucleic acid is a target nucleic acid (see, in particular, document 1, claims 1 to 4; document 2, page 13, line 5 to page 26, line 2; document 3, examples 2 and 3).</p>		

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	<p>Claims 1, 3, 5, 6, 9 to 11 and 18 to 20</p> <p>At the time of filing of this application, it was a known technique to use a support having separated compartments such as porous plates or strip wells in order to process a large number of samples simultaneously.</p> <p>In addition, in in situ PCR, the target nucleic acid is detected directly on the sample after PCR, but a judgment as to whether the amplified nucleic acid present in the PCR reaction solution is the target nucleic acid is made in normal PCR, and there is nothing preventing a person skilled in the art from employing a method carried out in normal PCR for the detection of nucleic acid amplified in in situ PCR.</p> <p>It would therefore be easy for a person skilled in the art to employ a support having separate compartments to process a large number of samples simultaneously and use said support to immobilize cells, and to make the judgment whether the amplified nucleic acid present in the PCR reaction solution is a target nucleic acid, in the in situ PCR set forth in documents 1 to 3.</p> <p>Claim 7</p> <p>At the time of filing of this application, it was a known technique in the field of devices for detecting targets on supports to adhere a reagent for detection beforehand to said support, therefore it would be easy for a person skilled in the art to conceive of immobilizing beforehand the gene fragments used for detection on the support of the inventions set forth in documents 1 to 3.</p>

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Box No. V**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement****Claim 8**

At the time of filing of this application, it was a known technique to use a DNA micro-array to detect the presence of a target nucleic acid.

It would therefore be easy for a person skilled in the art to conceive of the invention set forth in claim 8 of this application based on the inventions set forth in documents 1 to 3 and said known technique.

Claims 14 to 17

It would be easy for a person skilled in the art to conceive of employing the methods of detecting nucleic acids set forth in documents 1 to 3 to ascertain the presence of genes related to infectious diseases, cancer or hereditary diseases.